UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 22-cr-20471-WILLIAMS/MCALILEY

UNITED STATES OF AMERICA

v.

ANGELA MARIA GIRON,

Defendant.

_____/

FACTUAL PROFFER IN SUPPORT OF GUILTY PLEA

The United States Attorney, in and for the Southern District of Florida, the Department of Justice, Consumer Protection Branch (the government), and the defendant Angela Maria Giron ("the defendant"), agree that if this matter were to proceed to trial the government would be able to prove the following facts beyond a reasonable doubt. The parties further agree that these are not all of the facts that the government would prove if the case proceeded to trial but are sufficient to prove the charge of conspiracy as alleged in the Information in this case.

From in or about September 2015, through in or about March 2018, in Miami-Dade County, within the Southern District of Florida, and elsewhere, the defendant, Angela Maria Giron, did willfully, that is, with the specific intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate, and agree with persons known and unknown to the government to commit an offense against the United States by knowingly and with intent to defraud devising, and intending to devise, a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that they were false and fraudulent when made, and transmitting and causing to be transmitted, by

means of wire communications in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, for the purpose of executing the scheme, in violation of Title 18, United States Code, Section 1343.

During the conspiracy, the defendant was a licensed physician in Florida. AMB Research Center, Inc. ("AMB Research Center"), was a medical clinic located on West Flagler Street in Miami, Florida, that conducted clinical trials of new drugs for pharmaceutical companies and sponsors. Co-Conspirator 1, co-owner of AMB Research Center, served in roles including Director and lead study coordinator. Co-Conspirator 2, co-owner of AMB Research Center, served in roles including Director and study coordinator. Co-Conspirator 3 served in roles including data entry specialist and pharmacist.

The sponsor, a pharmaceutical company, developed and initiated a clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea ("CDAD clinical trial"). The Contract Research Organization ("CRO") was an organization that managed and oversaw the CDAD clinical trial for the sponsor. Co-Conspirator 1, on behalf of AMB Research Center, entered into a Clinical Trial Agreement ("CTA") with the CRO, which was acting on behalf of the sponsor, for the CDAD clinical trial.

The purpose of the conspiracy included the defendant and the co-conspirators unlawfully enriching themselves by: (a) causing the sponsor and/or the CRO to make payments on the contracts for the CDAD clinical trial, by making material false and fraudulent representations regarding, among other things, subject eligibility for and participation in the CDAD clinical trial, and (b) falsifying and fabricating documents, data, and other items relating to the CDAD clinical trial including subject informed consent forms, case histories, and data.

In or about October 2015, the defendant met Co-Conspirator 1, Co-Conspirator 2, and Co-Conspirator 3 (collectively "the Co-Conspirators") and agreed to be the clinical investigator, also known as the principal investigator, for the CDAD clinical trial at AMB Research Center. The defendant did not previously know the Co-Conspirators and was not familiar with AMB Research Center. The defendant signed the Food and Drug Administration ("FDA") Form 1572, Statement of Investigator, for the CDAD clinical trial. By signing the Form 1572, the defendant knew that as the clinical investigator she was required to, among other things, (1) conduct the CDAD clinical trial according to the study protocol and in compliance with all applicable federal regulations; (2) personally conduct and supervise the CDAD clinical trial; (3) obtain informed consent from the subjects; and (4) comply with the clinical trial protocol and federal regulation requirements relating to obtaining informed consent and the informed consent process.

The defendant's responsibilities also included all requirements regarding the qualification of the subjects; dispensing study medication; collecting and reporting data; reporting adverse events; and ensuring that all employees working on the study met those same obligations. In addition, the defendant was required, by regulation, to prepare and maintain case histories which were records relating to the CDAD clinical trial. The case histories included informed consent forms and medical records for each subject participating in the CDAD clinical trial, drug dispensation records, and records of all observations and other data pertinent to the CDAD clinical trial for each subject administered the study medication.

The defendant had the authority to delegate certain responsibilities relating to the CDAD clinical trial to the Co-Conspirators. The defendant delegated various responsibilities to the Co-Conspirators including (1) to Co-Conspirator 1 to complete/correct case report forms and electronic case report forms (eCRFs), maintain essential documents, administer and receive

questionnaires, reconcile stool diaries, conduct subject interviews, obtain vital signs, handle laboratory samples or perform ECGs, and scribe; (2) to Co-Conspirator 2 to maintain essential documents, administer and receive questionnaires, and reconcile stool diaries; and (3) to Co-Conspirator 3 to dispense medication, complete/correct case report forms and eCRFs, maintain essential documents, and handle laboratory samples or perform ECGs.

The defendant knew that she and AMB Research Center had been retained to perform the CDAD clinical trial honestly and accurately. The defendant also knew the sponsor could conduct an audit of the AMB Research Center trial site, and that the defendant and AMB Research Center staff were required to cooperate with the auditors and allow access to all study documentation and facilities.

The defendant and the co-conspirators knew that the subjects did not participate in the CDAD clinical trial according to the study protocol and federal regulations. For purposes of obtaining money by means of materially false and fraudulent pretenses, representations, and promises, the defendant and the co-conspirators created fraudulent and false records, including electronic case record files ("eCRFs"), which falsely represented that the subjects completed the informed consent form ("ICF") process which required the defendant to review the ICF with each subject and personally obtain the subject's written informed consent. The defendant also was required to always be involved in and have oversight of the informed consent process. In truth and fact, the defendant did not obtain written informed consent for any of the 22 subjects enrolled in the CDAD clinical trial and never went to AMB Research Center. Although the defendant did not have knowledge of it, as part of the conspiracy ten or more individuals' means of identification were used unlawfully or without authority in furtherance of the conspiracy.

The defendant and the co-conspirators falsified the data of enrolled subjects they knew did not participate in the CDAD clinical trial in compliance with the protocol. For example, the defendant knew she did not conduct the required clinical investigator assessments at visits 2, 4 and 5. To further facilitate the fraudulent scheme, the defendant knew that falsified and fraudulent information was submitted in case report forms and eCRFs falsely representing that the defendant had completed those required assessments according to the protocol. The defendant also knew that false information and data was submitted in the case report forms and eCRFs including false information and data representing that subjects had satisfied eligibility criteria to participate in the CDAD clinical trial, received and taken the study medication, and completed the required documents and journals.

Following an on-site audit by the sponsor of AMB Research Center in April 2017, the sponsor notified the FDA in writing of potential scientific misconduct by AMB Research Center. The Institutional Review Board ("IRB") for the CDAD clinical trial, an organization designated to monitor and review the clinical trial, sent AMB Research Center a copy of the sponsor's notification to the FDA. The defendant and Co-Conspirator 1 personally signed a letter dated May 7, 2017, titled "Site response to the Notification of Potential Scientific Misconduct" (sic) ("Response Letter"). Prior to signing the Response Letter, the defendant reviewed it with Co-Conspirator 1 and knew that it contained material false and fraudulent representations, including, among other things, that (1) the defendant was present for all subjects' informed consent and gave each subject the time to understand, read, and resolve any questions prior to signing the informed consent form; (2) AMB Research Center took special care with ICF signatures and the ICF process to ensure that subjects understood the study and its risks and could make an informed decision whether to participate; (3) all participating subjects had completed the study treatment and follow

up visits; and (4) the defendant and AMB Research Center site staff acted in accordance with the study protocol to the best of their knowledge. On May 8, 2017, Co-Conspirator 1 emailed the Response Letter from the Southern District of Florida to an employee of the IRB in North Carolina; the defendant was copied on that email.

The defendant knew that the CRO, on behalf of the sponsor, made the payments to AMB Research Center to conduct the CDAD clinical trial. The defendant further knew that AMB Research Center was responsible for paying the defendant for the CDAD clinical trial. On or about October 2, 2017, Co-Conspirator 1 sent an email from the Southern District of Florida to a CRO employee in North Carolina requesting AMB's final site payment which, based on Co-Conspirator 1's prior request for that final site payment, included payments for subjects who did not participate in the CDAD clinical trial in compliance with the study protocol. That same month, after AMB Research Center received from the CRO the final CDAD clinical trial payment, the defendant received from AMB Research Center her final check in the amount of $29,525.78 for the CDAD clinical trial. On or about October 20, 2017, the defendant negotiated that check. The defendant received a total amount of $58,119.60 for the CDAD clinical trial. AMB Research Center received over $250,000 but less than $550,000 for the CDAD clinical trial.

As a physician, the defendant abused her position of public or private trust and used her specialized skill as a medical doctor that significantly facilitated the commission and concealment of the fraud scheme and conspiracy.

The foregoing facts do not describe all the details of the scheme, or the defendant's complete knowledge of the scheme, but are offered for the limited purpose of establishing a sufficient basis to support the defendant's plea of guilty to the charge of conspiracy.

JUAN ANTONIO GONZALEZ
United States Attorney

Amanda Liskann (KC)
~~GUSTAV W. EYLER~~ Amanda Liskann
Director
U.S. Department of Justice
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ANGELA MARIA GIRON
DEFENDANT